Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0451291	07/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
William Newton Hospital	1300 E 5th Ave, Winfield, KS	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: A review of American Proficiency Institute (API) proficiency, Quality Control, Quality Assessment, and Interview with staff revealed the laboratory failed to verify the accuracy for the analyte Urine Total Protein for the 1 st event of and 1st event 2018 . Finding were as follows: 1. Based upon a review of API 1 st event 2017 Urine Total Protein received a 67% grade 1 st event 2018 67%. The laboratory failed to produce corrective action. This was confirmed in interview with General Supervisor #1 :from CMS form 209 hrs 07/10/2018 at 10:00 hrs
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: 1. A review of manufacturer's instructions for RecombiPlasTin , quality control and quality assessment records for coagulation, observation of the laboratory's equipment, and interview with staff revealed that the laboratory did not follow manufacturer's instructions for International Normalized Ratio (INR). Findings were as follows: a. Manufacturer's instructions from ACL Top 300 for the determination of INR state:

	"The normal PT is defined as the mean of the normal range and must be specifically determined for each lot of Recombiplastin , with the specific instrument/technique used for patient testing". b. Quality control and quality assessment records for ACL Top 300 coagulation analyzer at the time of survey (July 10, 2018) did not include determination of the PT patient normal range for the current lot of Reccombiplastin lot# N0972558 put into use 06/08/2018 and performed 308 patients. Therefore the accuracy or reliability can not be verified
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: A review of temperature and humidity records for the Respiratory Therapy area where the Blood Gas Analyzer was placed . Respiratory therapy failed to produce the documentation for the room temperature or humidity that the Roche blood gas analyzer was placed
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: 1. A review of manufacturer's instructions for RecombiPlasTin , quality control and quality assessment records for coagulation, observation of the laboratory's equipment, and interview with staff revealed that the laboratory did not follow manufacturer's instructions for International Normalized Ratio . Findings were as follows: a. Manufacturer's instructions from ACL Top 300 for the determination of INR state: "The normal PT is defined as the mean of the normal range and must be specifically determined for each lot of Recombiplastin , with the specific instrument/technique used for patient testing".At the time of the survey the laboratory failed to produce a normal patient mean for the calculation of the INR b. Quality control and quality assessment records for ACL Top 300 coagulation analyzer at the time of survey (July 10, 2018) did not include determination of the PT patient normal range for the current lot of Reccombiplastin lot# N0972558 put into use 06/08/2018 and performed 308 patients. Therefore the accuracy or reliability can not be verified
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results Finding were as follows a. Interview with General Supervisor from the CMS 209 07 /10//2018 at 09:30 hrs. confirmed the laboratory failed to have the policy, (All patients test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected).